

### **REMARKS/ARGUMENTS**

#### **Status of the Claims**

Claims 1-28 and 30-78 are pending in the present application. Claims 1, 10, 16, 20, 30, 34, and 37 have been amended to recite that the IFN- $\beta$  has the ability to bind to IFN- $\beta$  receptors. Claims 1, 10, 16, 20, 30, 32, 34, and 37 have further been amended to recite that the highly purified mannitol has a reducing activity of less than 20 parts per million. Support for these amendments may be found on lines 23-26 of page 5 and line 12 of page 11. No new matter has been added by way of amendment.

The Examiner is respectfully requested to withdraw the rejection and allow claims 1-28 and 30-78. In any event, the Examiner is requested to enter the above amendments for purposes of furthering prosecution. These amendments were not made earlier because Applicants earnestly believe that the specification is enabling for the breadth of the claims as originally drafted.

#### **The Rejection of the Claims under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn**

The rejection of claims 1-28 and 30-78 under 35 U.S.C. § 112, second paragraph, has been maintained. The rejection is respectfully traversed as applied to the amended claims for the reasons described below.

The Examiner argues that it is not clear what is encompassed by the phrase "biologically active IFN- $\beta$ ." Applicants maintain that one of skill in the art would understand the scope of this phrase as read in light of the supporting specification. Nevertheless, claims 1, 10, 16, 20, 32, 34, and 37 have been amended to recite that the biologically active IFN- $\beta$  has the ability to bind to IFN- $\beta$  receptors. Support for the amendment may be found on lines 12 of page 11 of the specification.

In view of the above arguments and amendments, all grounds for rejection under 35 U.S.C. § 112, second paragraph, have been overcome. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

The Rejection of the Claims under 35 U.S.C. § 112, First Paragraph, Should Be Withdrawn

The rejection of claims 1-28 and 30-78 under 35 U.S.C. § 112, first paragraph, for lack of enablement has been maintained. The rejection is respectfully traversed for the reasons described below.

The Office Action states that the specification fails to provide enablement commensurate in scope with the claims because the specification does not demonstrate the features of the highly purified mannitol. However, lines 24-26 of page 5 of the specification state that, "[t]he reducing activity of the highly purified mannitol is less than 20 parts per million USP as measured by the reducing activity assay described elsewhere herein." In order to expedite prosecution, claims 1, 10, 16, 20, 30, 32, 34, and 37 have been amended to recite this definition of highly purified mannitol. The specification teaches a method of making highly purified mannitol meeting the limitations of the claims on line 29 of page 5 through line 2 of page 6 and lines 2-4 of page 18. The specification also provides an assay for reducing activity on line 21 of page 20 through line 2 of page 21 of the specification. Accordingly, the specification provides guidance regarding the features of the highly purified mannitol to be used in the claimed compositions and methods, and provides a method for its production. In view of the guidance regarding the features of the highly purified mannitol and the guidance regarding a method of making highly purified mannitol having this feature, one of skill in the art would be able to make and use the invention without undue experimentation.

Furthermore, the Federal Circuit has held that the specification need only teach one mode of making and using the claimed invention to satisfy the enablement requirement. *Engel Industries Inc. v. The Lockformer Co.*, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991) *Johns Hopkins Univ. v. Cellpro, Inc.*, 47 USPQ2d 1705 (Fed. Cir. 1998) and *Durel Corp. v. Osram Sylvania Inc.* 59 USPQ2d 1238 (Fed. Cir. 2001). Claims 1-28 and 30-78 meet this requirement because the specification provides sufficient guidance to enable one of skill in the art to make highly purified mannitol having a reducing activity of less than 20 parts per million.

Accordingly, all grounds for rejection under 35 U.S.C. § 112, first paragraph, have been overcome. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Appl. No.: 10/010,448  
Amdt. dated February 28, 2005  
Reply to Office Action of October 28, 2004

## CONCLUSION

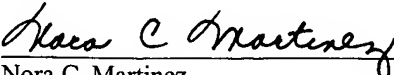
It is believed that all the rejections have been obviated or overcome and the claims are in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned agent.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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